

# Notice of Allowability

Application No.

10/723,654

Examiner

James H. Alstrum-Acevedo

Applicant(s)

KUMAR ET AL.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/12/06.
2. ☒ The allowed claim(s) is/are 44, 61-67, 77, 68-76, 50, 78-84, 94, 85-93, 60, 95-101, 111, 102-110 [Renumbered as 1-54].
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).


\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20061120; 20061201.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
JOHANN RICHTER  
SUPERVISORY PATENT EXAMINER  
20061600

***EXAMINER'S AMENDMENT***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Chris I. Halliday, Esq. on November 20, 2006 at approximately 5:00 pm EST and December 1, 2006 at approximately 11:25 am EST.

The application has been amended as follows:

- (1) In claims 44, 50, 60, 66-75, 83-92, and 100-109, delete "--, derivative, analog, homologue, or polymorph--" from line 9 in claims 44, 50, and 60 and from lines 2-3 in claims 66-75, 83-92, and 100-109.
- (2) In line 11 of claims 44, 50, and 60 insert "gel forming" before the word "polyethylene".
- (3) In line 1 of claims 62, 79, and 96 insert "gel forming" after the words "wherein the".
- (4) In line 11 of claim 44 insert "at about 3 to 40% by weight;" after the word "oxide".
- (5) In line 12 of claim 44 insert "at about 2 to 25% by weight," after the word "disintegrant".
- (6) In line 15 of claim 44 delete "46%" after the word "about" and replace with "50%."

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(7) In line 17 of claim 50, delete “46%” after the word “about” and replace with “50%.”

(8) In lines 7-8 of claim 40, delete “of any of the foregoing” and replace with --thereof--.

(9) In lines 9-10 of claims 50 and 60, delete “of any of the foregoing” and replace with --thereof--.

(10) In line 2 of claims 66-77, 83-94, and 100-111 delete “comprises” and replace with --is--.

### ***REASONS FOR ALLOWANCE***

The following is an examiner's statement of reasons for allowance: claims 44 and 61-77 are allowable, because the prior art does not teach or fairly suggest a therapeutic pharmaceutical composition comprising a mixture including (a) at least one opioid analgesic selected from a group of specific opioid analgesics (see, for example, “(a)” in claim 44 for the list of specific opioids); (b) a gel forming polyethylene oxide at about 3 to 40% by weight; (c) at least one disintegrant at about 2 to 25% by weight selected from a group of specific disintegrants (see, for example, “(c)” in claim 44); and (d) a nasal tissue irritant (e.g. a surfactant, such as sodium lauryl sulfate). These compositions are characterized by the property that less than about 50% of the total opioid analgesic in the composition is recovered when about 490 mg of the composition is contacted with 15 ml of water.

Claims 50 and 78-94 are allowable because the prior art does not teach or fairly suggest a therapeutic pharmaceutical composition comprising a mixture including (a) at least one opioid analgesic selected from a group of specific opioid analgesics (see, for

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example, “(a)” in claim 50 for the list of specific opioids); (b) a gel forming polyethylene oxide at about 3 to 40% by weight; (c) a surfactant at about 1 to 10% by weight; and (d) at least one disintegrant at about 2 to 25% by weight selected from a group of specific disintegrants (see, for example, “(d)” in claim 50). These compositions are characterized by the property that less than about 50% of the total opioid analgesic in the composition is recovered when about 490 mg of the composition is contacted with 15 ml of water.

Claims 60 and 95-111 are allowable because the prior art does not teach or fairly suggest a therapeutic pharmaceutical composition comprising a mixture including (a) at least one opioid analgesic selected from a group of specific opioid analgesics (see, for example, “(a)” in claim 60 for the list of specific opioids); (b) a gel forming polyethylene oxide at about 3 to 40% by weight; (c) at least one disintegrant at about 2 to 25% by weight selected from a group of specific disintegrants (see, for example, “(c)” in claim 60); and (d) sodium lauryl sulfate at about 1 to 10 percent by weight.

The above mentioned claims were found allowable upon (1) insertion of the term “gel-forming” in front of the word “polyethylene” in claims 44, 50, and 60; (2) insertion of specific weight limitations for components (b) (i.e. at about 3 to 40% by weight) and (c) (i.e. at about 2 to 25% by weight) in claim 44; (3) deletion of “46%” from lines 13 and 17 of claims 44 and 50, respectively; and (4) deletion of “, derivative, analog, homologue, or polymorph” from claims 44, 50, 60, 66-75, 83-92, and 100-109.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

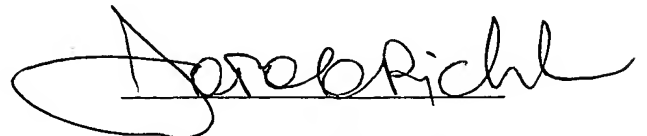
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.  
Patent Examiner  
Technology Center 1600

A handwritten signature in black ink, appearing to read 'Johann Richter', with a large, stylized loop at the beginning.

Johann Richter, Ph. D., Esq.  
Supervisory Patent Examiner  
Technology Center 1600